Attorney's Docket No.: 11926-015001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Vincent P. Stanton, Jr. Art Unit : 1655
Serial No. : 09/658,659 Examiner : Chakrabarti, A.
Filed : September 8, 2000
Title : GENE SEQUENCE VARIANCE IN GENES RELATED TO FOLATE METABOLISM HAVING UTILITY IN DETERMINING THE TREATMENT OF DISEASE

Commissioner for Patents
Washington, D.C. 20231

DECLARATION REGARDING INCORPORATION BY REFERENCE

1. Applicant hereby declares that the Sequence Listing appended hereto consists of the same sequence information incorporated by reference in the above-referenced application by reference to the GenBank® Accession Number U09806.

2. The sequence of SEQ ID NO:1 in the appended Sequence Listing is the same as that associated with GeneBank® Accession number U09806 on July 20, 1998, the filing date of U.S. Serial No. 60/093,484, from which the present application claims priority. This particular version of GeneBank® Accession Number U09806 is assigned the version identifier GI:945022. Exhibit A attached hereto is a printout from the GeneBank® Database of GenBank® Accession Number U09806 [GI: 945022]. This printout shows that GenBank® Accession Number U09806 [GI: 945022] replaced an earlier version of the sequence U09806 [GI:499223] on August 17, 1995. Exhibit B is a printout from the GeneBank® Database of Accession No. U09806 [GI:6174884] showing that it replaced GeneBank® Database of Accession No. U09806 [GI:945022] on November 2, 1999.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

November 13, 2002
Date of Deposit

Lenora H. Francis
Signature

Lenora H. Francis
Typed or Printed Name of Person Signing Certificate

3. In my Declaration regarding Incorporation By Reference filed on October 22, 2001 I mistakenly stated that the sequences in the Sequence Listing appended thereto were those incorporated by reference to GeneBank® Accession numbers in the above-referenced application. However, for GeneBank® Accession number U09806, the Sequence Listing appended to my October 22, 201 Declaration Regarding Incorporation by Reference had the incorrect version of GeneBank® Accession number U09806, namely, GeneBank® Accession number U09806 [GI:6174884] rather than GeneBank® Accession number U09806 [GI:945022]. This error was made without deceptive intent.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

November 13, 2002
Date

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20539163.doc

EXHIBIT A of DECLARATION for 09/658,659

1: U09806[gi:945022]

```
LOCUS       HSU09806                2187 bp    mRNA    linear   PRI 29-OCT-1999
DEFINITION  Homo sapiens methylenetetrahydrofolate reductase (MTHFR) mRNA,
            complete cds.
ACCESSION   U09806
VERSION     U09806.1  GI:945022
KEYWORDS    .
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Mammalia;
            Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 2187)
  AUTHORS   Goyette,P., Sumner,J.S., Milos,R., Duncan,A.M., Rosenblatt,D.S.,
            Matthews,R.G. and Rozen,R.
  TITLE     Human methylenetetrahydrofolate reductase: isolation of cDNA,
            mapping and mutation identification [published erratum appears in
            Nat Genet 1994 Aug;7(4):551]
  JOURNAL   Nature Genet. 7 (2), 195-200 (1994)
  MEDLINE   95004587
REFERENCE   2  (bases 1 to 2187)
  AUTHORS   Frosst,P., Blom,H.J., Milos,R., Goyette,P., Sheppard,C.,
            Matthews,R., Boers,G., den Heijer,M., Kluijtmans,L., van den
            Heuvel,L. and Rozen,R.
  TITLE     A canidate genetic risk factor for vascular disease: a common
            mutation in methylenetetrahydrofolate reductase
  JOURNAL   Nat. Genet. 10, 111-113 (1995)
REFERENCE   3  (bases 1 to 2187)
  AUTHORS   Rozen,R.
  TITLE     Direct Submission
  JOURNAL   Submitted (17-MAY-1994) Rima Rozen, Pediatrics, Human Genetics and
            Biology, McGill University - Montreal Children's Hospital, 2300
            Tupper St., Montreal, Quebec H3H 1P3, Canada
REFERENCE   4  (bases 1 to 2187)
  AUTHORS   Leclerc,D., Sibani,S. and Rozen,R.
  TITLE     Direct Submission
  JOURNAL   Submitted (29-OCT-1999) Pediatrics, Human Genetics and Biology,
            McGill University - Montreal Children's Hospital, 2300 Tupper St.,
            Montreal, Quebec H3H 1P3, Canada
  REMARK    Amino acid sequence update by submitter
COMMENT     [WARNING] On Nov 2, 1999 this sequence was replaced by a newer
            version gi:6174884.
            On Aug 17, 1995 this sequence version replaced gi:499223.
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EXHIBIT A

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Revised: July 5, 2002.

Search Nucleotide for Go Clear

Limits Preview/Index History Clipboard Details

Display default Save Text Add to Clipboard Get Subsequence

1: U09806. Synthetic constru...[gi:6174884] Links

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LOCUS       HSU09806                2196 bp    mRNA    linear   SYN 06-DEC-1999
DEFINITION  Synthetic construct methylenetetrahydrofolate reductase (MTHFR)
            mRNA, complete cds.
ACCESSION   U09806
VERSION     U09806.2  GI:6174884
KEYWORDS    .
SOURCE      synthetic construct
  ORGANISM  synthetic construct
            artificial sequences.
REFERENCE   1  (bases 1 to 2196)
  AUTHORS   Goyette,P., Sumner,J.S., Milos,R., Duncan,A.M., Rosenblatt,D.S.,
            Matthews,R.G. and Rozen,R.
  TITLE     Human methylenetetrahydrofolate reductase: isolation of cDNA,
            mapping and mutation identification
  JOURNAL   Nat. Genet. 7 (2), 195-200 (1994)
  MEDLINE   95004587
   PUBMED   7920641
REFERENCE   2  (bases 1 to 2196)
  AUTHORS   Frosst,P., Blom,H.J., Milos,R., Goyette,P., Sheppard,C.,
            Matthews,R., Boers,G., den Heijer,M., Kluijtmans,L., van den
            Heuvel,L. and Rozen,R.
  TITLE     A candidate genetic risk factor for vascular disease: a common
            mutation in methylenetetrahydrofolate reductase
  JOURNAL   Nat. Genet. 10 (1), 111-113 (1995)
  MEDLINE   95375773
   PUBMED   7647779
REFERENCE   3  (bases 1 to 2196)
  AUTHORS   Rozen,R.
  TITLE     Direct Submission
  JOURNAL   Submitted (17-MAY-1994) Rima Rozen, Pediatrics, Human Genetics and
            Biology, McGill University - Montreal Children's Hospital, 2300
            Tupper St., Montreal, Quebec H3H 1P3, Canada
REFERENCE   4  (bases 1 to 2196)
  AUTHORS   Leclerc,D., Sibani,S. and Rozen,R.
  TITLE     Direct Submission
  JOURNAL   Submitted (29-OCT-1999) Pediatrics, Human Genetics and Biology,
            McGill University - Montreal Children's Hospital, 2300 Tupper St.,
            Montreal, Quebec H3H 1P3, Canada
  REMARK    Amino acid sequence update by submitter
COMMENT     On Nov 2, 1999 this sequence version replaced gi:945022.
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EXHIBIT B

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Revised: July 5, 2002.

Oct 31 2002 16:00:17